

REMARKS

The rejection of Claims 9-11 and 15-17 under 35 U.S.C. § 103 as being obvious from the cited prior art is believed to have been improperly made and based on a misapplication of the references made possible only by hindsight knowledge of the present invention.

The Examiner says that Bartnik shows methods of treating skin of animals including dairy cattle with chlorhexidine and zinc oxide, and the Examiner says that powder forms are specified but he acknowledges that chlorhexidine gluconate (CHG) is exemplified and that chlorhexidine acetate (CHA) is not exemplified. The Examiner has apparently given very broad interpretations and analyses to the teachings of Bartnik, and these broad interpretations and analyses can only be made by the use of hindsight knowledge of the present invention.

The Bartnik reference indeed does disclose treating of animal skin with a powder, but (and this is a very pertinent and important but), the powder MUST BE water adsorbable AND FURTHER WITH RESPECT TO THE TREATMENT OF TEATS OF COWS, THE BARTNIK REFERENCE ACTUALLY TEACHES ONLY THE APPLICATION OF A LIQUID OR PASTE TO THE TEATS OF A COW. There is simply no suggestion whatsoever, even remote, in the Bartnik reference of treating the teats of a cow with A POWDER.

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In those instances when a powder is used (and that DOES NOT include application to the teats of a cow for as mentioned above the Bartnik reference TEACHES ONLY THE APPLICATION OF A LIQUID OR PASTE TO THE TEATS OF A COW), the Bartnik reference says at column 5, lines 39-49:

"Although there are in fact numerous solids (sic) powders, they are often limited in their application. THIS IS ALWAYS (emphasis added) the case when the powder-forming solid material is not resorbable by the body, so that powder articles interfere with the healing process or have to be eliminated by the body in the course of the healing process. BY CONTRAST (emphasis added) vulnerary powders using the carrier materials of the invention ideally satisfy the requirement of instantly closing the wound as required while, at the same time, allowing it to breathe, ABSORBING (emphasis added) the exudate and acceleratiang (sic) the granulation process."

It is very clear that in the embodiments of the Bartnik reference in which powders are used, the powders MUST be water soluble. The exudate of a wound is water based, with water being the solvent. Bartnik makes it abundantly clear that the powders of the invention MUST be dissolved by the exudate and thereby absorb the exudate. Bartnik specifically notes that the powder

is dissolved and interacts with the exudate, and at column 5 lines 54-55, the Bartnik reference says "a kind of artificial scab is formed WITH THE AID OF THE WOUND FLUID" (emphasis added).

Thus, when the Bartnik reference is really examined, it becomes very clear why, as the Examiner has acknowledged, the Bartnik reference exemplifies chlorhexidine gluconate (which is water soluble) but does not exemplify chlorhexidine acetate (which is NOT water soluble). The powder of the Bartnik reference MUST be water soluble.

In addition, the whole basis of the Bartnik reference involves the use of oligomeric esters of lactic acid and/or glycolic acid. These materials are water soluble or will absorb water to form a paste or film on the skin of the animals to which the materials are applied. In addition, these materials are resorbable carriers which are distinguished by their high body resorbability (see column 1, lines 33-35 and column 2 lines 11-24 of the Bartnik reference). As explicitly taught in the Bartnik reference, the oligomers "can be mixed with other powder-form components used in skin and wound care in order to enhance certain desired effects, for example, TO ENHANCE THE ABSORBING EFFECT (emphasis added) of the powder" (see column 6 line 65 to column 7 line 1). There is no suggestion, even remote, in the Bartnik reference of using a non-soluble, inert carrier such as

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cornstarch and a non-soluble chlorhexidine component.

The Examiner notes that Bartnik shows methods of treating skin of animals including dairy cattle. The Examiner apparently, however, does not pursue or at worse totally ignores the actual teaching of the Bartnik reference which is in fact that the skin of dairy cattle is to be treated with a carrier comprising an oligomer that is (1) water soluble, (2) is applied in the form of a liquid or paste and (3) is resorbable by the body of the animal being treated. Lets look at what else the Bartnik reference teaches that the Examiner has apparently chosen to overlook. At column 7 lines 37-52 of the Bartnik reference, it is explicitly stated that attempts have been made to provide relatively long-lasting protection to teats of cows through the formation of films on the teats of the cow using polymer compounds. It is pointed out however that at the next milking the teat has to be carefully cleaned to remove such films. Then, it is explicitly stated, "According to the invention, It (sic) is possible for the first time, by regulating the permanence of the carrier material to the desired time of 20 to 12 hours, to apply standard disinfectants simply and safely in the carriers of the invention." What are those carriers. They are water soluble oligomers that are resorbable by the body of the cow. They are certainly not inert, powdered carriers such as cornstarch. The

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Bartnik reference continues, "a protective FILM (emphasis added) being formed which, at the time of the next milking, but not until then, has been ABSORBED (emphasis added) by the udder tissue and, hence does not interfere with the next milking." (See column 7, lines 49-52) Claim 3 of the Bartnik reference explicitly and emphatically requires that the composition is applied "to the cow udders as a thinly liquid to paste-like composition." There is no suggestion whatsoever of applying a powder to the teats of a cow as recited in the claims of the present application.

The Bartnik reference specifically teaches that when treating the teats of a cow, the carrier is a water soluble oligomer that is resorbable by the body of the cow. And importantly, the Bartnik reference further specifically teaches that the composition is applied to the udders of the cow AS A THINLY LIQUID TO PASTE-LIKE composition. In addition, the other ingredients, including disinfectants, must also be water soluble so that the carrier and the other ingredients will be resorbed by the body of the cow. It becomes evident why the Bartnik reference exemplifies chlorhexidine gluconate, inasmuch as that compound is water soluble. It also becomes very evident why the Bartnik reference DOES NOT exemplify chlorhexidine acetate, inasmuch as that compound is not water soluble.

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It is made abundantly clear by the Bartnik reference that in the treatment of teats of cows, (1) the carrier (the oligomers) must be water soluble, (2) the composition must be applied as a thinly liquid to paste-like material, and (3) any added material must also be water soluble. That is why chlorhexidine acetate is not exemplified in the Bartnik reference, it IS SIMPLY NOT WATER SOLUBLE. There is no suggestion whatsoever in the Bartnik reference of a method as claimed in the present application wherein the teats of the cow are treated with a dry, powdered composition containing only particulate powdered materials. In the present invention, the teats of a cow are treated with a powdered composition containing a carrier which (1) is an INERT POWDERED carrier, preferably cornstarch, (2) is not soluble in water, and (3) is not resorbable by the body of the animal. It is indeed INERT. There is simply no suggestions, even remote, in the Bartnik reference of treating the teats of cows with a powdered material in which the powdered carrier is an inert, powdered carrier that is non-soluble. Nor is there any suggestion in the Bartnik reference of treating the teats of a cow with a powdered material containing particulate, powdered forms of a chlorhexidine-containing material such as chlorhexidine acetate.

The Examiner apparently cites the Modak reference as

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supposedly showing that it would have been obvious to modify the powders of the Bartnik reference to include chlorhexidine acetate in place of the chlorhexidine gluconate which is exemplified in the Bartnik reference. Such a modification would be specious inasmuch as the Modak reference specifically teaches that all of the compositions of that reference are to be applied to the skin as a liquid suspension. There is no suggestion whatsoever in the Modak reference of applying a dry powder to the skin. Thus, even if one on first blush thinks about using chlorhexidine acetate in place of chlorhexidine gluconate, there would be nothing to suggest the application of a dry powder to the skin. But, on second blush, one skilled in the art would find that on its face the use of chlorhexidine acetate in place of chlorhexidine gluconate of the Bartnik reference is completely illogical unless the Modak reference also teaches some magical way of making chlorhexidine acetate soluble, which, of course, it does not. The Bartnik reference specifically teaches using a powder that is soluble and will be resorbed by the body of a cow when it is placed on the skin of the cow.

It is submitted that the Examiner is without doubt using hindsight knowledge of the present invention in even citing the Modak reference. The Modak reference DOES NOT suggest the application of a powder composition to the skin of an animal.

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The composition of the Modak reference may well contain a powder and even chlorhexidine acetate, but the powder and the chlorhexidine acetate are NOT applied to the skin as a powder. Instead, they are suspended in a fluid, and the fluid suspension is applied to the skin. There is no suggestion whatsoever in the Modak reference of application of a dry powdered composition to the skin of an animal.

The Examiner cites Examples 4 and 5 of the Modak reference as showing chlorhexidine acetate and chlorhexidine gluconate being used with zinc oxide and corn starch. But, both Examples 4 and 5 show the preparation of a suspension of those materials. The suspensions were centrifuged, washed with water and dried. But then what was done with those materials? To answer that question, one must look at Examples 6A-6E and all the other Examples of the Modak reference. In Examples 6A-6E all the compositions of Examples 1-5, including of course the compositions of Examples 4 and 5, were mixed with and suspended in water. Example 11 of the Modak reference then shows results of tests of in Vitro efficacy of the suspensions.

Every one of the remaining Examples of the Modak reference show the application of the suspensions to skin and other articles. There is absolutely no suggestion, however, of applying dry powders of any kind to anything in the Modak



reference. Thus, if anything, the Modak reference may suggest using a suspension containing chlorhexidine acetate, but there is no motivation or suggestion whatsoever of using a dry powdered composition containing chlorhexidine acetate to the skin of an animal.

As mentioned previously, it is illogical to suggest the combination of the Modak reference with the Bartnik reference at least as far as suggesting that it would be obvious to substitute chlorhexidine acetate for chlorhexidine gluconate. The Modak reference does not provide a method of magically converting chlorhexidine acetate into a resorbable material, and the Bartnik reference specifically requires a resorbable material which chlorhexidine gluconate is. But, even if the impossibility of using chlorhexidine as a resorbable material is overlooked, the combination of the Modak reference with the Bartnik reference would not correct the basic deficiency of the Bartnik reference in the first place. The Bartnik reference fails completely to suggest the application of a dry powdered composition containing a dry, inert, powdered carrier to the teats of a cow. The Bartnik reference explicitly teaches the application of a liquid or paste to the teats of a cow, and the liquid or paste must contain a water soluble carrier. The Modak reference augments the teaching of the Bartnik reference in teaching the application

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of aqueous suspensions to the skin. There is absolutely no suggestion in the Modak reference of applying a dry powdered composition to the skin.

To reiterate, the Modak reference does not even remotely suggest that chlorhexidine acetate can be resorbed by the skin of an animal. And, in fact, it cannot. Thus, it is illogical to combine the Modak reference with the Bartnik reference. Further, neither the Bartnik reference or the Modak reference even remotely suggests application of a dry powder composition to the teats of a cow. The Bartnik reference specifically teaches the application of a thinly fluid to past-like composition to the teats, and Modak teaches a composition for application to skin but does not exemplify application to the teats of a cow, and more importantly does not suggest application of a powder, but rather a liquid suspension.

In the present case, the Examiner has clearly ignored the relevant teachings of the two cited prior art references, and, with hindsight reconstruction of the present invention, come to the improper conclusion that the present invention would have been obvious to one of ordinary skill in view of the two references. It is impermissible within the framework of 35 U.S.C. § 103 to first ascertain what applicant has done and then, by hindsight reconstruction, pick and choose from any one

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reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such a reference fairly suggests to one of ordinary skill in the art. In re Wesslau, 147 USPQ 391 (CCPA 1965) and In re Shuman et al., 150 USPQ 54 (CCPA 1966).

In the present case, the Examiner has clearly ignored relevant teachings of both the Bartnik reference and the Modak reference. The Examiner has ignored, or at least completely overlooked, the teaching in the Bartnik reference that (1) the antimicrobial that is added to the oligomers must be soluble and resorbable by the skin of an animal and (2) the carrier must be an oligomer that is soluble and is very much an active carrier that is resorbed by the skin. The Modak reference teaches the use of chlorhexidine acetate in a powder composition, but the Examiner has ignored, or at least completely overlooked, the teaching of the Modak reference that such a composition is applied in the form of an aqueous suspension. Further, there is no suggestion in the Modak reference that chlorhexidine acetate is soluble in water, which it of course is not, nor is there any suggestion that the chlorhexidine acetate is resorbable by the skin of an animal, which it is not.

Further, for the Examiner's combination of the Modak reference with the Bartnik reference to be proper, there must be

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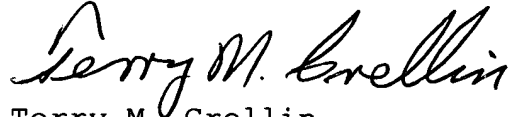
some suggestion of the desirability of the modifications that are supposedly suggested by the Modak reference. To paraphrase the holding of In re Laskowski, 10 USPQ 2nd 1397 (CAFC 1989), the mere fact that the prior art could possibly be modified to make the claimed invention does not make the modifications obvious unless the prior art suggests the desirability of the modification. Wherein is there any suggestion in the Modak reference of the desirability of modifying the process of the Bartnik reference to use chlorhexidine acetate? There can be no suggestion of such an illogical modification inasmuch as Bartnik specifically requires a soluble and resorbable material, and chlorhexidine acetate is simply not soluble and not resorbable. And further wherein is there any suggestion in the Modak reference of the desirability of modifying the process of the Bartnik reference to apply a powdered material to the teats of a cow? The Modak reference makes no suggestion whatsoever of applying a dry powdered composition to the skin of anything let alone the teat of a cow. In fact, the Modak reference explicitly teaches and exemplifies the application of liquid suspensions and not powdered material to the skin. There is certainly no suggestion of the desirability of modifying the process of the Bartnik reference to apply a dry powdered composition containing a dry, particulate, inert carrier in place of the liquid soluble

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carriers called for in the Bartnik reference.

The application is believed to be in proper formal condition, and the claims clearly distinguish over the cited prior art. Accordingly, the application is believed to be in condition for immediate allowance, and an early notice to that effect is respectfully solicited.

Respectfully submitted,



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